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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/803,235

03/17/2004

Elizabeth Dzeng

Stanford S03-060

5638

39843

7590

06/12/2008

BELL & ASSOCIATES

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SAN FRANCISCO, CA 94131

EXAMINER

GIBSON, ROY DEAN

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

06/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/803,235	Applicant(s) DZENG ET AL.	
	Examiner Roy D. Gibson	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-14 and 34-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 34-36 is/are allowed.
- 6) ☒ Claim(s) 12, 37-41 and 45-50 is/are rejected.
- 7) ☒ Claim(s) 13, 14 and 42-44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 June 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Formal Matters

In light of newly found art prosecution is reopened and this Office action is non-final.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12, 37, 38, 39, 40 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Dae(6,231,594). Dae discloses a heat exchange catheter system for cooling a target organ, the heat exchange catheter system adapted for placement within an anatomical structure of a subject, comprising:

(a) a first elongate tubular body (Figure 8, outer tube # 80) having a proximal end and a distal end, (b) a second elongate tubular body (Figure 8, inner tube) having a proximal end and a distal end, (c) a balloon (3 lobes 60, 62 and 64 as in Figures 7-11) defining a lumen (Figures 10 and 11 with supply lumen # 70 and return lumen # 72) in fluid communication with both the first elongate tubular body and the second elongate tubular body so as to form a continuous fluid pathway, the lumen further comprising a thermal exchange composition, wherein the thermal exchange composition flows within the continuous fluid pathway formed by the second elongate tubular body, the first elongate tubular body and the balloon lumen and wherein the thermal exchange

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composition is selected from the group consisting of a solid, a liquid, (d) a transducer (temperature sensor, col. 21, lines 51-57) and wherein the balloon, when inflated has a longitudinally disposed groove (space between lobes) upon its outer surface and is adapted to conform in shape and size to the interior of the anatomical structure such that when placed within the anatomical structure and inflated, the outer surface of the balloon is at least partially in contact with the inner surface of the anatomical structure providing a heat exchange surface by which heat is exchanged between the anatomical structure and interior of the balloon, and whereby the target organ adjacent to the anatomical structure is thereby cooled (23, line 58-col. 24, line 37).

Further to claims 38-41, Dae discloses the heat exchange catheter system wherein the balloon is shaped and sized for placement in the anatomical structure selected from the group consisting of: the esophagus, the oral cavity, the nasopharyngeal cavity, the auditory tube and tympanic cavity, the sinus of the brain, the arterial system, the venous system, the larynx, the trachea, the bronchus, the stomach, the duodenum, the ileum, the colon, the rectum, the bladder, the ureter, the ejaculatory duct, the vas deferens, the urethra, the uterine cavity, the vaginal canal, and the cervical canal; and wherein the target organ is selected from the group consisting of: the myocardium of the heart, the lungs, the thymus, the thyroid, the liver, the pancreas, the kidney, the uterus, the ovary, the testis, the prostate, and the brain; and wherein the balloon conducts heat from the anatomical structure to the thermal exchange composition (these claim limitations are intended use only and do not effect the

structure of the device except perhaps its size, which is generally not a patentable feature when taken alone).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 45-50 are rejected under 35 U.S.C. 103(a) as being obvious over Dae.

Dae discloses the target organ is cooled by a circulating fluid within the heat exchange catheter, but fails to specifically disclose the rate of cooling. However, the examiner maintains that it would have been obvious to a skillful artisan to determine the appropriate rate by routine experimentation based upon the organ to be cooled and that since the rates claimed are sufficiently broad, no critically is disclosed by applicant.

Allowable Subject Matter

Claims 34-36 are allowed.

Claims 13, 14 and 42-44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on Tu-Th, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Roy D. Gibson/
Primary Examiner
Art Unit 3739

June 9, 2008